

***REMARKS***

The Office Action dated July 13, 2005 has been carefully reviewed and the following remarks are made in response thereto. Claims 16 and 18 have been amended. Support for the amendment “identifying a subject with facial pain caused by trigeminal neuralgia in need of treatment thereof” can be found throughout the specification, and, for example, at page 7, lines 3-5; page 7, lines 18-22; page 3, lines 11-12; page 4, lines 4-6.

In view of the amendments to the claims and the following remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

***Status of the Claims***

1. Claims 16-19 are pending.
2. The Examiner has rejected claims 16-19 under 35 U.S.C. § 102(b) as purportedly anticipated by U.S. Patent No. 5,714,468 to Binder.
3. No claims were allowed.

***The Rejection of Claims 16-19 under 35 U.S.C. § 102(e)***

Applicants acknowledge, with appreciation, the withdrawal of the rejection of claims 16-19 as allegedly being anticipated by U.S. Pat. No. 6,464,986 to Aoki *et al.* under 35 U.S.C. § 102(e).

***The Rejection of Claims 16-19 under 35 U.S.C. § 102(b)***

Claims 16-19 stand rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by U.S. Pat. No. 5,714,468 to Binder (the '468 patent). Applicants respectfully traverse this rejection for the following reasons.

As stated above, claim 16 has been amended. The '468 patent does not teach – inherently or otherwise – each and every element of the claimed invention. Specifically, the '468 patent does not teach a) *identifying* a subject with facial pain caused by trigeminal neuralgia in need of treatment thereof; b) that said subject is *in need of treatment* of the *facial pain* caused by trigeminal neuralgia; c) *multifocal injections* of a therapeutically effective amount of botulinum toxin *to an afflicted area of the face, excluding the brow and upper or lower eyelid*; and d) treating the facial pain caused by trigeminal neuralgia with botulinum toxin. Should the Office maintain this rejection, Applicants respectfully requests that the Office indicate where these claim elements are taught in the '468 patent.

As previously stated, the '468 patent has nothing to do with what Applicants have invented. It is therefore respectfully asserted that the '468 patent is improperly applied against the pending claims because it does not teach, inherently or explicitly, each and every element of the pending claims.

The '468 patent is directed to methods for the treatment of headache pain. Headache pain is not the same as facial pain caused by trigeminal neuralgia. Example 1 of the '468 patent is entitled "Administration of Botulinum Toxin A to Reduce Headache Pain in Humans"

[emphasis added]. The example indicates that over a period of 6 months, 162 patients received 1 to 2 injections of Botulinum toxin A. Of the patients who received the injections, 11 reported a prior case history of headache pain. This group of 11 patients is referred to as the “headache group” patients. See column 8, lines 28-30. One of the patients in the headache group had previously been diagnosed as having trigeminal neuralgia (see column 8, lines 31-32). This patient had previously been treated pharmacologically without substantial reduction of her symptoms. See column 8, lines 39-42. All of the 11 patients in the headache group, including the patient that had previously been diagnosed as having trigeminal neuralgia, reported that “they were either free of headaches or suffered substantially reduced headache pain...following treatment [with botulinum toxin]” See column 8, lines 43-46.

Thus, nothing whatsoever in the ‘468 patent teaches what is currently claimed. The ‘468 patent does not teach treating facial pain caused by trigeminal neuralgia. The patient in the headache group in Example 1 who was previously diagnosed as having trigeminal neuralgia was treated for headache pain, not facial pain caused by trigeminal neuralgia – and it was her headache pain that was reduced. Contrary to what the Office Action asserts, the ‘468 patent does not teach treating facial pain caused by trigeminal neuralgia. The ‘468 patent does not teach identifying a subject with facial pain caused by trigeminal neuralgia in need of treatment thereof. The ‘468 patent does not teach administering to said subject multifocal injections of a therapeutically effective amount of botulinum toxin to an afflicted area of the face, excluding the brow and upper or lower eyelid, of said patient, thereby reducing or eliminating said facial pain caused by trigeminal neuralgia. Thus, there is nothing in the ‘468 patent that teaches or even

remotely suggests the treatment of facial pain caused by trigeminal neuralgia. At best, the '468 patent teaches the use of Botulinum toxin to treat headache pain, but this is simply not the same as what Applicants have invented and currently claim.

The Office Action at page 4 alleges that the '468 patent "teaches a method of alleviating pain from local areas of the face including relief of headache as well as such trigeminal neuralgia by administration of botulinum toxin" and cites column 6, lines 58-67; column 7, lines 1-3; Table 1(b), column 2. Applicants have very carefully reviewed the cited passages and are unable to find any teaching, as asserted in the Office Action of "alleviating pain from local areas of the face including relief of headache as well as such trigeminal neuralgia." Nowhere in the '468 patent is there any reference made to "alleviating pain from local areas of the face ... as well as such trigeminal neuralgia" as is asserted in the Office Action. Applicants respectfully request that the Office indicate specifically where this teachings exists in the '468 patent.

The Office Action refers to the passage beginning at column 6, lines 58-67 and continuing to column 7, lines 1-3 as allegedly teaching what is claimed. Applicants simply do not agree that this or any other passage in the '468 patent rises to the level of anything approaching an anticipatory teaching or suggestion. The passage is reproduced below:

For example, as shown in the data presented in the Examples, the method of the invention was effective in reducing headache pain even in persons who only received an extramuscular injection of presynaptic neurotoxin. Moreover, reduction of headache pain was unexpectedly observed even in patients whose pain was causally related to vascular or neurological components; e.g., classical migraine, trigeminal neuralgia and trauma headache. However, those of ordinary skill in the art will recognize that additional therapeutic benefits may be achieved through introduction of the presynaptic neurotoxins of the invention into

musculature (particularly in the back) where muscle spasm or strain is present.  
[emphasis added]

Thus, this passage asserts that the data presented in the Examples shows that headache pain may be reduced. This has nothing to do with treating facial pain caused by trigeminal neuralgia. The reference made in the passage to trigeminal neuralgia is simply an indication that some headaches are causally related to trigeminal neuralgia. This is not a teaching of treating facial pain caused by trigeminal neuralgia. Indeed, the passage goes on to suggest administering presynaptic neurotoxins to the back, where muscle spasm or strain is present. It is respectfully and emphatically asserted that this does not even come close to suggesting what Applicants have invented and currently claim.

Consequently, the '468 patent does not anticipate claims 16-19. Reconsideration and withdrawal of the rejection is requested.

#### ***Objections to the Claims***

Claim 18 stands objected to for the following informalities: "about 10 to 200 LD 50 units" should be "about 10 to 200 LD<sub>50</sub> units." Claim 18 has been amended to show the requested subscript. Withdrawal of the objection is requested.

***Objections to the Specification***

The disclosure stands objected to because the trademarks identified in the specification are not capitalized. The disclosure has been amended to capitalize all trademarks. Withdrawal of the objection is requested.

***Conclusion***

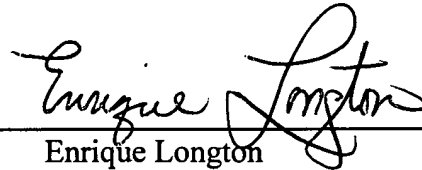
Applicants respectfully request reconsideration and withdrawal of the outstanding rejections and early allowance of the pending claims. Should the Examiner find that a telephone interview would further prosecution of the application, she is invited to contact the undersigned at her convenience.

The Commissioner is authorized to charge any additional fees associated with this filing, or credit any overpayment, to Deposit Account No. 13-3250. **EXCEPT** for issue fees payable under 37 C.F.R. § 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 13-3250. This paragraph is intended to be an **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with C.F.R. § 1.136(a)(3).

Respectfully submitted,

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By: \_\_\_\_\_



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Dated: October 12, 2005

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